REMARKS/ARGUMENTS

Claims 1-12 and 27-35 are pending in this Application.

Claims 1-5, 7, 8, 10-12, and 27-35 are currently amended. Applicants respectfully submit that support for the claim amendments can be found throughout the specification and the drawings.

Claims 1-12 and 27-35 remain pending in the Application after entry of this Amendment. No new matter has been entered.

In the Office Action, claims 1-12 and 27-35 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Claims 1-12 and 27-35 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 1-12, 34, and 35 stand rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. Claims 1-5, 7-12, and 27-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0023057 (hereinafter "Goodwin"). Claims 6 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goodwin, in view of non-patent literature entitled "Industries can issue digital certificates to hike security" by Lawrence D. Casiraya (hereinafter "Casiraya").

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Applicants respectfully traverse the rejections to claims 1-12 and 27-35 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

The Office Action alleges that "there is no support for having a first, second, third, fourth, or fifth in addition to having one or more of each type of interface." Applicants respectfully submit that this allegation stems from some confusion expressed in the Office Action as to whether the specification discloses how a user can 1) graphically setup and define a stability study and 2) graphically implement the stability study by gathering data.

As recited in amended claim 1, information that enables display of interfaces in a first set of graphical user interfaces are forwarded to a first client computer. As recited, a first interface in the first set of one or more graphical user interfaces enables users of the client

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computer to create stability studies by specifying requirements that need to be fulfilled for the stability studies. Applicants respectfully submit that the specification supports this first interface that enables users of the client computer to create stability studies by specifying requirements that need to be fulfilled for the stability studies. For example, paragraph [0040] of the specification states "Figs. 5A, 5B, 5C, 5D, and 5E depict interfaces used to define test interval, storage conditions, and monitoring and item stability specifications." (Emphasis added). Accordingly, several examples of a first interface "that enables users of the client computer to create stability studies by specifying requirements that need to be fulfilled for the stability studies" as shown.

The Office Action concludes on page 3 that "[t]he specification has only provided disclosure that a user is presented with an interface that requests the user to input information to satisfy the requirements that are being displayed to the user through the interface." This conclusion is completely unsupported and is relevant to the confusion as to how a user can 1) graphically setup and define a stability study and 2) graphically implement the stability study by gathering data. Even by a casual glance at the above mentioned figures illustrates the specification provide a first set of one or more graphical user interfaces (e.g., FIGS. 5 et seq. and FIGS. 6 et seq.) that enable a user to 1) graphically setup and define a stability study. For example, FIG. 5A entitled "Test Interval Plan" enables the user to provide information defining or establishing a test interval for a stability study, such as dialog 504 entitled "Set Up Test Interval" for the test frequency, duration, and period.

Moreover, FIG. 4 clearly illustrates that before a stability study is launched in step 408, a stability study is setup, planned, and tested (created) in steps 402, 404, and 406. FIGS. 5A, 5B, 5C, 5D, and 5E are discussed in the specification following how "[i]n a stage 402, the building blocks or templates for a stability study are initially set up" as described in paragraph [0038]. Additionally, the remaining steps of FIG. 4 disclose the use of a second set of one or more graphical user interfaces that enable a user to 2) graphically implement the stability study by gathering data (see FIGS. 7A and 7B).

In paragraph [0039], referring to FIGS. 5A, 5B, 5C, 5D, and 5E, the specification states that "[a]lthough these interfaces are shown, it will be understood that other interfaces will

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be appreciated." Thus, Applicants respectfully submit that there is adequate support for user-created workflows and user-specified business rules. In paragraph [0016], the specification discloses that "[e]mbodiments of the present invention provide a graphical user interface (GUI) that outputs forms and workflows that are created to establish and monitor all facets of a stability study." The workflows provide information on actions that should be taken during the study, such as shown in FIG. 5A that enables the user to provide information defining or establishing a test interval and FIG. 5B enables the user to define monitoring specifications (e.g., actions that should be taken during the study).

The Office Action further alleges that "there is no disclosure eve of generating an interface." Applicants respectfully disagree. The claims are part of the specification, and claim 1 as originally presented included the feature of "generating one or more interfaces." Moreover, paragraph [0006] provides "[t]he method comprising: generating one or more interfaces for the stability study." Paragraph [0020] provides that "[t]hese interfaces are automatically generated." Paragraph [0052] provides the following:

> [0053] Fig. 6B depicts an interface 620 that defines information for material sources according to one embodiment of the present invention. Interface 620 defines information needed in order to select or request batches as a basis for the stability study. In selecting an existing batch material, a batch number and lot number may be inputted. In requesting a new batch material, the plant and/or plant recipe and version may be input. A workflow may then be generated and output that includes a notification to create a batch according to the inputted information so that stability samples can be taken from the batch. (Emphasis added)

Accordingly, Applicants respectfully submit that each of the interfaces recited in amended claim 1 are supported by the specification. Thus, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph to claims 1-12 and 27-35.

To address a few minor points:

On page 6, the Office Action alleges that "there is no support for a plurality of stability studies." However, paragraph [0001] provides that "[t]he present invention relates generally to shelf life for stability studies." (Emphasis added). Merely because

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embodiments are explained for the purposes of clarity by stepping through stages of one stability study does not negate the fact that the disclosure supports such variations and indicates that these variations are apparent to one of ordinary skill in the art. Moreover, paragraph [0038] reads:

> [0038] In a stage 402, the building blocks or templates for a stability study are initially set up. An interface is outputted that defines requirements for the stability study setup and actions that need to be performed. For example, the interface provides information defining test interval plans; storage condition plans; storage packages; and monitoring and item stability specifications. The components of the interfaces may be <u>reused for multiple studies</u> and may be used for the same item or different item. <u>Base and overlay components are used to create new test interval plans and monitoring and item stability test specifications. A base specification may be used and overlaps may be created to capture variations in the base specifications.</u> (Emphasis added).

On page 6, the Office Action alleges that "there is not support the method [sic] to be carried out one more than one display device." Again, this is unfounded because the specification provides in paragraph [0075] that "other configurations having <u>more</u> or fewer components than the system depicted in Fig. 8 are possible." (Emphasis added).

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejections to claims 1-12 and 27-35 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph as being indefinite.

In regard to claims 1-12 and 27-35, the Office Action states that "the Examiner is uncertain of why the applicant discloses a first stability study when there are not subsequent stability studies. While Applicants do not necessarily agree with the Examiner's uncertainty, Applicants have amended the claims to recited the phrase "at least one stability study."

In regard to claims 1, 27, and 34, the Office Action states that the term "enable" is not a positive recitation." While Applicants do not necessarily agree with the Examiner's assertion, Applicants have amended the claims to positively recite "information configured to display" user interfaces that enable users to perform specific actions. The Examiner asserts that "enabling" a user to perform a specific task is no different than "allowing" a user to perform the

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task, but fails to explain why either is indefinite or why the forwarding of such information as recited in the claims would be suggested as optional or not otherwise required to be performed.

In regard to the remaining rejections, while Applicants do not necessarily agree with the Examiner's assertions, Applicants have amended the claims for the sake of clarity and readability.

Thus, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph to claims 1-12 and 27-35.

Claim Rejections Under 35 U.S.C. § 101

Applicants respectfully traverse the rejections to claims 1-12 and 34-35 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claim Rejections Under 35 U.S.C. § 103(a)

Applicants respectfully traverse the rejections to claims 1-12 and 27-34 and request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) based on Goodwin and Casiraya. Applicants, however, respectfully submit that a prima facie case of obviousness has not been established by the evidence presented in the Office Action. As reiterated by the Supreme Court in KSR International Co. v. Teleflex Inc. (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007), the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). The factual inquiries enunciated by the Court are as follows:

(A) Determining the scope and content of the prior art;

(B) Ascertaining the differences between the claimed invention and the prior art; and

(C) Resolving the level of ordinary skill in the pertinent art.

To reach a proper determination under 35 U.S.C. § 103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual

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information, the Examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. (M.P.E.P. § 2142).

Applicants respectfully submit that Goodwin and Casiraya, either individually or in combination, fail to disclose one or more of the claim limitations recited in each of claims 1-12 and 27-35. These differences, along with other difference, establish that the subject matter as a whole of claims 1-12 and 27-35 would not have been obvious at the time of invention to a person of ordinary skill in the art.

For example, amended claim 1 recites the feature of "generating, at a data processing device, a second set of one or more graphical user interfaces for the at least one stability study based on the set of requirements that need to be fulfilled for the at least one stability study, the set of workflows associated with the plurality of stages of the at least one stability study, and the set of business rules for the at least one stability study, wherein the second set of one or more graphical user interfaces define the set of requirements for the at least one stability study." As recited in amended claim 1, the set of requirements that need to be fulfilled for the at least one stability study, the set of workflows associated with the plurality of stages of the at least one stability study, and the set of business rules for the at least one stability study are provided by a user via a first set of graphical user interfaces. As a results, "forms and workflows are created [and output] to establish and monitor all facets of a stability study." (Application: Paragraph [0016]).

Rather than ascertaining the differences between the claimed invention and the prior art, the Office Action simply alleges on page 12 that "the type of data that is being input does not affect how the method is carried out or how the interfaces interact with the user." Applicants again respectfully submit that this allegation stems from some confusion expressed in the Office Action as to whether the specification discloses how a user can 1) graphically setup and define a stability study and 2) graphically implement the stability study by gathering data. As recited, interfaces are generated that define the requirements of a given stability study based on the information provided by a user. As recited, interfaces are also provided that enable users to create those interfaces the requirements of a given stability study. On page 12, the Office Action concludes that "the claimed invention is merely providing a user with a plurality of

interfaces to input the requested information through the user of prompts." Yet, amended claim 1 recites method for both setting up a stability study using a first set of interfaces <u>and</u> inputting information requested by the previously created stability study which is substantially different from Goodwin's alleged disclosure.

Accordingly, Applicants respectfully submit that Goodwin fails to disclose each and every claim limitation as recited in amended claim 1. Applicants further respectfully submit that none of the cited references cure the above-discussed deficiencies of Goodwin, and thus, amended claim 1 is allowable over the cited references.

Applicants respectfully submit that independent claims 27 and 34 are allowable for at least a similar rationale as discussed above for the allowability of claim 1, and others. Applicants respectfully submit that dependent claims 2-12, 28-33, and 35 that depend directly and/or indirectly from independent claims 1, 27, and 34 respectively, are also allowable for at least a similar rationale as discussed above for the allowability of the independent claims. Applicants further respectfully submit that the dependent claims recite additional features that make the dependent claims allowable for additional reasons.

Unless otherwise specified, amendments to the claims are made for the purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof.

While Applicants do not necessarily agree with the prior art rejections set forth in the Office Action, these amendments may be made to expedite issuance of the Application. Applicants reserve the right to pursue claims to subject matter similar to those pending before the present Amendment in co-pending or subsequent applications.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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